

ACACIA POLLEN - acacia pollen injection  
 ALDER, WHITE POLLEN - alnus rhombifolia pollen injection  
 ALFALFA POLLEN - medicago sativa pollen injection  
 ALKALI BLITE POLLEN - suaeda moquinii pollen injection  
 ALTERNARIA - alternaria alternata injection  
 AMERICAN ELM POLLEN - ulmus americana pollen injection  
 ARIZONA ASH POLLEN - fraxinus velutina pollen injection  
 ARROYO WILLOW POLLEN - salix lasiolepis pollen injection  
 ASPEN POLLEN - populus tremuloides pollen injection  
 ASPERGILLUS FUMIGATUS - aspergillus fumigatus injection  
 AUSTRALIAN PINE POLLEN - casuarina equisetifolia pollen injection  
 BAHIA GRASS POLLEN - paspalum notatum pollen injection  
 BASSIA POLLEN - bassia hyssopifolia pollen injection  
 BEECH POLLEN - fagus grandifolia pollen injection  
 BLACK COTTONWOOD POLLEN - populus balsamifera ssp. trichocarpa pollen injection  
 BLACK OAK POLLEN - quercus velutina pollen injection  
 BLACK WALNUT POLLEN - juglans nigra pollen injection  
 BLACK WILLOW POLLEN - salix nigra pollen injection  
 BOTRYTIS - botrytis cinerea injection  
 BOTTLEBRUSH POLLEN - callistemon citrinus pollen injection  
 BOX ELDER MAPLE POLLEN - acer negundo pollen injection  
 BURNING BUSH POLLEN - kochia scoparia pollen injection  
 BURROBRUSH POLLEN - hymenoclea salsola pollen injection  
 BURWEED MARSHELDER POLLEN - iva xanthifolia pollen injection  
 CALIF. BLACK WALNUT POLLEN - juglans californica pollen injection  
 CALIFORNIA JUNIPER POLLEN - juniperus californica pollen injection  
 CALIFORNIA SCRUB OAK POLLEN - quercus dumosa pollen injection  
 CANARY GRASS POLLEN - phalaris arundinacea pollen injection  
 CANDIDA - candida albicans injection  
 CANYON RAGWEED POLLEN - ambrosia ambrosioides pollen injection  
 CARELESS WEED POLLEN - amaranthus palmeri pollen injection  
 CATTLE EPITHELIA - bos taurus skin injection  
 CEPHALOSPORIUM - cephalosporium roseum injection  
 CHAETOMIUM - chaetomium globosum injection  
 CHEAT GRASS POLLEN - bromus secalinus pollen injection  
 CHERRY BIRCH POLLEN - betula lenta pollen injection  
 CHINESE ELM POLLEN - ulmus pumila pollen injection  
 CLADOSPORIUM - cladosporium herbarum injection  
 COAST LIVE OAK POLLEN - quercus agrifolia pollen injection  
 COAST MAPLE POLLEN - acer macrophyllum pollen injection  
 COAST SAGE POLLEN - artemisia californica pollen injection  
 COCKLEBUR POLLEN - xanthium strumarium pollen injection  
 COCKROACH, AMERICAN - periplaneta americana injection  
 COCKROACH, GERMAN - blatella germanica injection  
 COMMON SAGE POLLEN - artemisia tridentata pollen injection  
 CORN POLLEN POLLEN - zea mays pollen injection  
 COTTON LINTERS - cotton fiber injection  
 COTTONSEED - cotton seed injection  
 CULTIVATED OAT POLLEN - avena sativa pollen injection  
 CURVULARIA - cochliobolus lunatus injection  
 CYPRESS, ARIZONA POLLEN - cupressus arizonica pollen injection  
 DANDELION POLLEN - taraxacum officinale pollen injection  
 DATE PALM POLLEN - phoenix dactylifera pollen injection  
 DESERT RAGWEED POLLEN - ambrosia dumosa pollen injection  
 DOCK, YELLOW POLLEN - rumex crispus pollen injection  
 DOG HAIR - canis lupus familiaris hair injection  
 EASTERN COTTONWOOD POLLEN - populus deltoides pollen injection  
 EASTERN SYCAMORE POLLEN - platanus occidentalis pollen injection  
 EASTERN WHITE PINE POLLEN - pinus strobus pollen injection  
 ENGLISH PLANTAIN POLLEN - plantago lanceolata pollen injection

ENGLISH WALNUT POLLEN - *juglans regia* pollen injection  
 EPICOCUM - *epicoccum nigrum* injection  
 EUCALYPTUS POLLEN - *eucalyptus globulus* pollen injection  
 EUROPEAN OLIVE POLLEN - *olea europaea* pollen injection  
 FALSE RAGWEED POLLEN - *ambrosia acanthicarpa* pollen injection  
 FLAXSEED - flax seed injection  
 FREMONT COTTONWOOD POLLEN - *populus fremontii* pollen injection  
 FUSARIUM - *haematonectria haematococca* injection  
 GAMBELS OAK POLLEN - *quercus gambelii* pollen injection  
 GIANT RAGWEED POLLEN - *ambrosia trifida* pollen injection  
 GLYCEROL-SALINE CONTROL - glycerin injection  
 GOAT EPITHELIA - *capra hircus* skin injection  
 GRAMA GRASS POLLEN - *bouteloua gracilis* pollen injection  
 GRAY (WHITE) BIRCH POLLEN - *betula populifolia* pollen injection  
 GREASEWOOD POLLEN - *sarcobatus vermiculatus* pollen injection  
 GREEN ASH POLLEN - *fraxinus pennsylvanica* pollen injection  
 GUINEA PIG EPITHELIA - *cavia porcellus* skin injection  
 HACKBERRY POLLEN - *celtis occidentalis* pollen injection  
 HAMSTER EPITHELIA - *mesocricetus auratus* skin injection  
 HARD MAPLE POLLEN - *acer saccharum* pollen injection  
 HAZELNUT POLLEN - *corylus americana* pollen injection  
 HELMINTHOSPORIUM SATIVUM - *cochliobolus sativus* injection  
 HOG EPITHELIA - *sus scrofa* skin injection  
 HORSE EPITHELIA - *equus caballus* skin injection  
 HOUSE DUST - house dust injection  
 IODINE BUSH POLLEN - *allenrolfea occidentalis* pollen injection  
 JOHNSON GRASS POLLEN - *sorghum halepense* pollen injection  
 JUTE - *corchorus capsularis* fiber injection  
 KAPOK - *ceiba pentandra* fiber injection  
 KARAYA GUM - karaya gum injection  
 KOELERS GRASS POLLEN - *koeleria macrantha* pollen injection  
 LAMBS QUARTERS POLLEN - *chenopodium album* pollen injection  
 LENS SCALE POLLEN - *atriplex lentiformis* pollen injection  
 LINDEN POLLEN - *tilia cordata* pollen injection  
 LOMBARD POPLAR POLLEN - *populus nigra* pollen injection  
 MELALEUCA POLLEN - *melaleuca quinquenervia* pollen injection  
 MESQUITE POLLEN - *prosopis juliflora* pollen injection  
 MONILIA - *chrysonilia sitophila* injection  
 MOUNTAIN CEDAR POLLEN - *juniperus ashei* pollen injection  
 MOUSE EPITHELIA - *mus musculus* skin injection  
 MUCOR - *mucor racemosus* injection  
 MUGWORT SAGE POLLEN - *artemisia vulgaris* pollen injection  
 MUSTARD POLLEN - *brassica rapa* pollen injection  
 NETTLE POLLEN - *urtica dioica* pollen injection  
 ORRIS ROOT - *iris germanica* var. *florentina* rhizome injection  
 PALO VERDE POLLEN - *cercidium floridum* ssp. *floridum* pollen injection  
 PECAN POLLEN - *carya illinoensis* pollen injection  
 PENICILLIUM - *penicillium chrysogenum* var. *chrysogenum* injection  
 PEPPER TREE POLLEN - *schinus molle* pollen injection  
 PHOMA - *pleospora betae* injection  
 POVERTY WEED POLLEN - *iva axillaris* pollen injection  
 PRIVET POLLEN - *ligustrum vulgare* pollen injection  
 PULLULARIA - *aureobasidium pullulans* var. *pullutans* injection  
 PUSSY WILLOW POLLEN - *salix discolor* pollen injection  
 QUACKGRASS POLLEN - *elymus repens* pollen injection  
 RABBITBUSH POLLEN - *ambrosia deltoidea* pollen injection  
 RED ALDER POLLEN - *alnus rubra* pollen injection  
 RED CEDAR POLLEN - *juniperus virginiana* pollen injection  
 RED MAPLE POLLEN - *acer rubrum* pollen injection  
 RED MULBERRY POLLEN - *morus rubra* pollen injection

RED OAK POLLEN - *quercus rubra* pollen injection  
REDROOT PIGWEED POLLEN - *amaranthus retroflexus* pollen injection  
RHIZOPUS - *rhizopus arrhizus* var. *arrhizus* injection  
RIVER/RED BIRCH POLLEN - *betula nigra* pollen injection  
ROCKY MTN. JUNIPER POLLEN - *juniperus scopulorum* pollen injection  
ROUGH MARSHELDER POLLEN - *iva annua* var. *annua* pollen injection  
RUSSIAN OLIVE POLLEN - *elaagnus angustifolia* pollen injection  
RUSSIAN THISTLE POLLEN - *salsola kali* pollen injection  
RUST, WHEAT - *puccinia striiformis* var. *striiformis* injection  
SALT CEDAR POLLEN - *tamarix gallica* pollen injection  
SALT GRASS POLLEN - *distichlis spicata* pollen injection  
SANDBUR RAGWEED POLLEN - *ambrosia chamissonis* pollen injection  
SHAD SCALE POLLEN - *atriplex confertifolia* pollen injection  
SHAGBARK HICKORY POLLEN - *carya ovata* pollen injection  
SHEEP SORREL POLLEN - *rumex acetosella* pollen injection  
SHORTLEAF PINE POLLEN - *pinus echinata* pollen injection  
SILVER MAPLE POLLEN - *acer saccharinum* pollen injection  
SILVER RAGWEED POLLEN - *dicoria canescens* pollen injection  
SISAL - *agave sisalana* fiber injection  
SLENDER RAGWEED POLLEN - *ambrosia tenuifolia* pollen injection  
SMOOTH BROME POLLEN - *bromus inermis* pollen injection  
SMUT, CORN - *ustilago maydis* injection  
SMUT, JOHNSON GRASS - *sporisorium cruentum* injection  
SMUT, WHEAT - *tillecia caries* injection  
SPRING BIRCH POLLEN - *betula occidentalis* pollen injection  
STEMPHYLIUM - *pleospora tarda* injection  
SUGAR BEET POLLEN - *beta vulgaris* pollen injection  
SUNFLOWER POLLEN - *helianthus annuus* pollen injection  
SWEET GUM POLLEN - *liquidambar styraciflua* pollen injection  
TAG ALDER POLLEN - *alnus incana* ssp. *rugosa* pollen injection  
TOBACCO LEAF - tobacco leaf injection  
TREE OF HEAVEN POLLEN - *ailanthus altissima* pollen injection  
UTAH JUNIPER POLLEN - *juniperus osteosperma* pollen injection  
VELVET GRASS POLLEN - *holcus lanatus* pollen injection  
WESTERN JUNIPER POLLEN - *juniperus occidentalis* pollen injection  
WESTERN RAGWEED POLLEN - *ambrosia psilostachya* pollen injection  
WESTERN SYCAMORE POLLEN - *platanus racemosa* pollen injection  
WESTERN WATERHEMP POLLEN - *amaranthus tuberculatus* pollen injection  
WESTERN WHEATGRASS POLLEN - *pascopyrum smithii* pollen injection  
WHITE ASH POLLEN - *fraxinus americana* pollen injection  
WHITE HICKORY POLLEN - *carya alba* pollen injection  
WHITE MULBERRY POLLEN - *morus alba* pollen injection  
WHITE OAK POLLEN - *quercus alba* pollen injection  
WHITE POPLAR POLLEN - *populus alba* pollen injection  
WING SCALE POLLEN - *atriplex canescens* pollen injection  
WINTERFAT POLLEN - *krascheninnikovia lanata* pollen injection  
WORMWOOD SAGE POLLEN - *artemisia absinthium* pollen injection  
YELLOW PINE POLLEN - *pinus ponderosa* pollen injection

Allermed Laboratories, Inc.

## **WARNINGS**

**This allergenic product is intended for use by physicians who are experienced in the administration of allergenic extracts, and the emergency care of anaphylaxis, or for use under the guidance of an allergy specialist.**

**This allergenic extract is not directly interchangeable with other allergenic extracts. The initial dose must be based on skin testing as described in the dosage and administration section of this insert. Patients being switched from other types of extracts, such as alum precipitated extracts, should be started as though they were coming under treatment for the first time. Patients should be instructed to recognize adverse reaction symptoms and cautioned to contact the physician's office if reaction symptoms occur. As with all allergenic extracts, severe systemic reactions may occur. In certain individuals these systemic reactions may occur. In certain individuals these reactions may be life threatening. Patients should be observed for at least 20 minutes following treatment, and emergency measures as well as personnel trained in their use should be immediately available in the event of a life threatening reaction.**

**This product should not be injected intravenously (see Dosage and Administration). Refer also to the Warnings, Precautions, Adverse Reactions and Overdosage sections below.**

## **DESCRIPTION**

Allergenic extract contains the aqueous extractables from allergenic source material in extracting solution containing 0.25% sodium chloride, 0.125% sodium bicarbonate, and 50% glycerol. 0.4% phenol is added as a preservative. The weight by volume value shown on the label is a measurement of extract concentration, rather than extract potency. Extracts for which U.S. standards exist are labeled in allergy units, in addition to w/v strength.

## **CLINICAL PHARMACOLOGY**

Positive skin tests with allergenic extract are the result of histamine release from mast cells sensitized with allergen specific IgE. The exact mechanisms by which immunotherapy relieves symptoms of allergy are still under investigation. Elevations in allergen-specific IgG antibodies and an increase in the activity of T suppressor lymphocytes appear to be some of the immunologic changes that occur from hyposensitization.<sup>1,2,3</sup>

## **INDICATIONS AND USAGE**

Allergenic extract may be used as a diagnostic skin test reagent in persons suspected of being sensitive to the allergenic source material from which the extract is made. Skin tests should be used in conjunction with a thorough allergic history to establish the relevance of a given allergen in the etiology of allergic disease.<sup>4,5,6</sup>

Immunotherapy with allergenic extract is indicated in persons suffering from allergic rhinitis, bronchitis, conjunctivitis, urticaria and asthma. The therapeutic efficacy of allergenic extract has been proven in ragweed, grass, and mountain cedar pollinosis, cat-induced asthma and hypersensitivity to hymenoptera venoms.<sup>7-12</sup>

Immunotherapy may be used along with or exclusive of antihistamines and other medications used to control allergic symptoms.

## **CONTRAINDICATIONS**

Allergenic extract should not be administered to a non-allergic person. However, there are no absolute contraindications to the use of allergenic extract for treatment in appropriate individuals. Relative contraindications include: **EXTREME SENSITIVITY TO AN ALLERGEN** - Determined from the allergic history, or from previous anaphylaxis following skin testing or subcutaneous injection; **AUTOIMMUNE DISEASE** - Individuals with autoimmune disease may be at risk, due to the possibility of routine immunizations exacerbating symptoms of the underlying disease; **PREGNANCY** - In limited controlled studies of women receiving allergenic extract during conception and throughout all trimesters of pregnancy, no evidence was found that extract is harmful to the fetus or mother. However, because of the known pharmacologic action of histamine on uterine muscle, any treatment that might result in the release of significant amounts of this mediator should be avoided if possible<sup>13</sup>. See Precaution #4; **MYOCARDIAL INFARCTION** - Patients who have experienced a recent myocardial infarction may not be able to tolerate immunotherapy. As in all of the above circumstances, the benefit to risk ration must be carefully evaluated; **BLEEDING DIATHESIS** - Patients with a bleeding tendency should not be tested or treated with allergenic extract, unless the physician responsible believes that such procedures are safe to perform.

Allergenic extract should be temporarily withheld from patients if any of the following conditions exist: (1) severe symptoms of hay fever and/or asthma; (2) infection or flu accompanied by fever; and (3) exposure to excessive amounts of clinically relevant allergens prior to skin testing or immunotherapy.

## **WARNINGS**

The only approved method for determining hypersensitivity to Allermed Laboratories Allergenic Extracts is by diagnostic skin testing (See **DOSAGE AND ADMINISTRATION — DIAGNOSIS**).

Physicians who administer allergenic extract should have emergency medication and equipment available to treat anaphylaxis<sup>14</sup>. See Precautions, Adverse Reactions and Overdosage below.

To reduce the risk of anaphylaxis, the following measures must be observed:

1. Concentrated extract must be diluted before use for intradermal skin testing and for beginning immunotherapy. It should never be injected intravenously during testing or treatment procedures.
2. Patients who are highly sensitive, determined from clinical findings and test results, may require that treatment start with a very weak concentration of extract, such as 1:10,000,000 v/v.
3. The dosage of fresh (new) extract given to a patient receiving maintenance injections must be reduced to one-fourth the amount given from the previous (old) lot (See Immunotherapy, last paragraph).
4. Patients who are transferred to standardized extract after previous treatment with unstandardized extract must be skin tested with serial dilutions, starting with a 1:100,000 v/v dilution of the standardized extract, to determine a safe, non-reacting starting dose.
5. Patients who are transferred to this extract after treatment with alum precipitated or other modified extract must re-start injections with the beginning recommended dose of this extract.

## **PRECAUTIONS**

1. Extract should be stored at 2°C to 8°C since higher temperatures may adversely affect the stability of the product. Do not freeze.
2. After the needle is inserted subcutaneously, the plunger should be withdrawn slightly to check for the presence of blood in the syringe. If blood is observed, a new injection should be prepared and given at another site, observing the same precautions.
3. Treatment with beta-blocking drugs may make patients refractory to the usual dose of epinephrine, in the event epinephrine is required to control an adverse allergic reaction.
4. **PREGNANCY CATEGORY C.** Allergenic extract. Animal reproduction studies have not been conducted with allergenic extract. It is also not known whether allergenic extract can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Allergenic extract should be given to a pregnant woman only if clearly needed.
5. **PATIENT INSTRUCTIONS:** Patients should be instructed to remain in the physician's office for at least 20 minutes after skin testing and after each treatment injection, and immediately notify the physician if symptoms of a generalized reaction or shock occur.
6. **CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY:** Long term studies have not been conducted with allergenic extracts to determine their potential for carcinogenesis, mutagenesis, and impairment of fertility.
7. **LACTATION:** Data are not available on the secretion of allergenic extract in human milk and it is not known what affect this might have on the nursing infant.
8. **PEDIATRIC USE:** The dose of allergenic extract recommended for children is the same as that used for adults, except in the injection of large doses of extract for treatment. In this case, the amount of extract given to a child may be modified so that the discomfort of the injection is minimized.

## **ADVERSE REACTIONS**

**Local Reactions:** The occurrence of a hive 5 to 15 minutes after the subcutaneous injection of extract does not require a reduction in dosage. However, a local reaction with edema larger than 2 cm in diameter or swelling and redness that persist for several hours or longer indicates that too much extract has been given. Treatment should be altered as follows:

1. Additional injections should not be given until all evidence of the reaction has disappeared.
2. The next injection administered should be 50% of the last non-reacting dose or less, depending upon the size and severity of the local reaction.
3. Subsequent injections should be continued at the reduced dosage unless the physician responsible for treatment believes that it is safe to increase the dose, and that possible clinical improvement would result from the administration of a larger dose of extract.

**Systemic Reactions:** Systemic (generalized) reactions may range from a mild exacerbation of the patient's allergic symptoms to hives, anaphylactic shock, or even death from anaphylaxis. The reaction usually occurs 5 to 20 minutes after injection. As a rule, the more quickly a reaction develops, the more serious it is likely to become. Symptoms may include sneezing, coughing, itching, shortness of breath, abdominal cramps, vomiting, diarrhea, tachycardia, hypotension and respiratory failure in severe cases. The reaction is usually stopped by the subcutaneous injection of Epinephrine HCL 1:1,000 (See Overdosage below). The oral administration of antihistamines and the placement of a tourniquet proximal to the injection site are helpful adjuncts. In the event that additional measures are required, it may be necessary to treat the patient for BRONCHOSPASM with intravenous aminophylline, intravenous fluids and corticosteroids; for HYPOTENSION with vasopressors, volume repletion, isoproterenol and corticosteroids; for

LARYNGEAL OBSTRUCTION with oxygen and tracheostomy and for CARDIAC ARREST with cardiopulmonary resuscitation and other appropriate measures.

Immunotherapy after anaphylaxis should be continued if the cause of the reaction can be identified and appropriate precautions taken to insure that a subsequent reaction does not occur.

## OVERDOSAGE

A strong local reaction to the injection of extract may be treated with oral antihistamines and the local application of a cold compress. The dosage must be reduced and additional extract must not be given until all evidence of the reaction has disappeared.

A systemic reaction following the injection of extract must be treated immediately. Reported procedures include (Ref. #4, vol. 2, p. 888):

1. 0.01 mL/kg up to 0.2 mL of aqueous epinephrine HCL 1:1000 subcutaneously at the injection site of antigen.
2. 0.01 mL/kg up to 0.3 mL of aqueous epinephrine HCL 1:1000 subcutaneously at another site.
3. Diphenhydramine intravenously or intramuscularly, 1.25 mg/kg up to 50 mg.
4. Tourniquet above the injection site of antigen.

Specific reactions:

1. Bronchospasm: intravenous aminophylline 4 mg/kg up to 500 mg given over 10 to 15 minutes, aqueous hydrocortisone 5 mg/kg up to 200 mg, oxygen.
2. Laryngeal edema: oxygen, intubation, tracheostomy.
3. Hypotension: vasopressors, fluids, corticosteroids.
4. Cardiac arrest: resuscitation, sodium bicarbonate, defibrillation, antiarrhythmia medications.

## DOSAGE AND ADMINISTRATION

**Diagnosis:** Concentrated extract may be used for scratch or prick testing providing the patient is not extremely sensitive. In this case, the extract should be diluted 10 fold before a scratch or prick test is performed. Extract for intradermal testing must be used as follows:

- a. Patients with a negative scratch or prick test: Patients who do not react who do not react to a valid scratch or prick test should be tested intradermally with 0.05 mL of a 1:1000 v/v dilution of the concentrate. If the test is negative, a second test should be performed with 0.05 mL of a 1:100 v/v dilution or concentrate.
- b. Patients with positive scratch or prick tests: It is not advisable to perform an intradermal skin test if the patient has a positive scratch or prick test.
- c. Patients tested only by the intradermal method: Patients suspected of being highly allergic should be tested with 0.05 mL of a 1:100,000 v/v dilution of the concentrate. A negative test should be followed by repeat tests using 10 fold stronger concentrations until the maximum dose of 0.05 mL of a 1:100 v/v dilution is reached.

## Interpretation of Results

### Scratch and Prick Test

A negative test shows only a slight red area at the site of scarification or prick penetration. Positive tests are scored as follows:

- 1+ Erythema with 5 mm wheal
- 2+ Erythema with a 5-10 mm wheal
- 3+ Erythema with a 10-15 mm wheal
- 4+ Erythema with a wheal 15 mm (or larger) with pseudopodia

### Intradermal Test

A negative test shows no change in the appearance and size of the 5 mm wheal created by the I.D. injection of 0.05 mL of extract.

Positive tests are scored as follows:

- 1+ Erythema 10-20 mm with a 5-10 mm wheal
- 2+ Erythema 20-30 mm with a 5-10 mm wheal
- 3+ Erythema 30-40 mm with a 10-15 mm wheal
- 4+ Erythema greater than 40 mm with a 15 mm wheal (or larger) with pseudopodia

## Immunotherapy

Allergenic extract should be administered subcutaneously in the outer aspect of the upper arm using a sterile tuberculin syringe and needle. The skin should be cleaned with 70% alcohol and aseptic technique should be observed in removing the extract from the vial. Care must be taken to avoid injecting the extract into a blood vessel because of the risk of anaphylaxis.

Concentrated extract must be diluted before administration to new patients. A 1:100,000 v/v dilution of concentrate is usually satisfactory to start treatment. However, as a precaution against overdose, a skin test with the intended starting dose should be done to help evaluate the patient's sensitivity to the product. If the skin response is larger than 5 mm edema/15 mm erythema, the extract

is too strong and must be diluted before it is given subcutaneously. The doses shown in the Dosage Schedule (Table 1) below are recommended unless the patient's skin test response and allergic history indicates that more dilute extract should be used. Little is known about the required accumulated dosage of allergen that is needed to relieve symptoms. However, studies have shown that high dose immunotherapy is efficacious in the treatment of allergic rhinitis and asthma. For this reason, treatment with extract from Vial #5 is recommended, providing the patient can tolerate the extract without experiencing local or systemic reactions. Treatment with Vial #6 may be used for patients who have not had adverse reactions to extract in Vial #5 and who require more concentrated extract to control or relieve symptoms.

Patients who have received allergenic extract for maintenance therapy SHOULD NOT be given the same dose from a fresh vial of extract. IT IS ADVISABLE TO REDUCE THE DOSAGE OF FRESH EXTRACT TO ONE-FOURTH THE AMOUNT GIVEN FROM A PREVIOUS LOT OF EXTRACT MADE AT THE SAME CONCENTRATION AND BY THE SAME FORMULA.

Table 1 - Suggested Dosage Schedule

No.	Vial #1 1:100,000 w/v frequency twice weekly mL	Vial #2 1:10,000 w/v frequency twice weekly mL	Vial #3 1:1,000 w/v frequency once weekly mL	Vial #4 1:100 w/v frequency once weekly mL	Vial #5 1:10 w/v frequency every two-four weeks mL	Vial #6 Concentrate frequency every two-four weeks mL
1	0.025	0.025	0.025	0.025	0.025	0.025
2	0.05	0.05	0.05	0.05	0.05	0.05
3	0.10	0.10	0.10	0.10	0.10	0.10
4	0.15	0.15	0.15	0.15	0.15	0.15
5	0.20	0.20	0.20	0.20	0.20	0.20
6	0.25	0.25	0.25	0.25	0.25	0.25
7	0.30	0.30	0.30	0.30	0.30	0.30

## SUPPLIED

Allergenic extract is supplied in dropper vials for scratch or prick testing and in 10, 30, and 50 mL vials for bulk use.

## WARRANTY

Allermed Laboratories, Inc. certifies that allergenic extract prepared within the Laboratories meets the safety and sterility standards of the F.D.A. Because the Laboratories have no control over the conditions under which extract is used, or the purposes intended, neither a good nor a bad effect following its administration is warranted.

The users of this product should be aware of the potential dangers involved in the injection of allergenic extract and accept the risk of any consequences resulting from such injections.

No representatives of the Laboratories may change this warranty whether written, oral or implied. The buyer or user must assume full responsibility for the product after it leaves the premises of the Laboratories.

## REFERENCES

1. Levy, D.A., L.M., Lichtenstein, E.O. Goldstein and K. Ishizaka. Immunologic and cellular changes accompanying the therapy of pollen allergy. J. Clinical Investigations. 50:360, 1971.
2. Evans, R., H. Pence, H. Kaplan and R. Rocklin. The effect of immunotherapy on humoral and cellular response in ragweed hayfever. J. Clinical Investigations. 57:1378, 1976.
3. Ishizaka, K. Cellular events in the IgE antibody response. Adv. In Immunology. 23:50, 1976.
4. Middleton, Elliott, Jr., C.E. Reed and E.F. Ellis (Eds.) Allergy, Principles and Practice Vols. 1&2, C.V. Mosby 1978.
5. Sheldon, J.M., R.G. Lovell and K.P. Matthews. A Manual of Clinical Allergy. W.B. Saunders, 1967.
6. Nelson, H.S. Diagnostic procedures in allergy. I. Allergy skin testing. Ann. Allergy. 51:411, 1983.

7. Norma, P.S., W.L. Winkenwerder and L.M. Lichtenstein. Immunotherapy of hay fever with ragweed antigen E: comparisons with whole pollen extract and placebos. *J. Allergy*. 42:93, 1968.
8. Milner, F.H. and E.C. Tees. Specific sensitivity to individual grass pollens in some hay fever patients. *Clinical Allergy*. 2:83, 1972.
9. Frankland, A.W. and R. Augustine. Grass pollen antigens effective in treatment. *Clinical Science*. 23:95, 1962.
10. Pence, H.L., D.Q. Mitchell, R.L. Greely, B.R. Updegraff and H.A. Selfridge. Immunotherapy for mountain cedar pollinosis: a double-blind controlled study. *J. Allergy and Clinical Immunology*. 58:39, 1976.
11. Taylor, W.W., J.L. Ohman, Jr. and F.C. Lowell. Immunotherapy in cat-induced asthma. Double-blind trial with evaluation of bronchial responses to cat allergen and histamine. *J. Allergy and Clinical Immunology*. 61:283. 1978.
12. Lichtenstein, L.M., M.D. Valentine and A.K. Sobotka. Insect allergies. The state of the art. *J. Allergy and Clinical Immunology*. 61:268, 1978.
13. Metzger, W.J., E. Turner and R. Patterson. The safety of immunotherapy during pregnancy. *J. Allergy and Clinical Immunology*. 61:268. 1978.
14. Ouellette, J.J. Emergency management of allergic reactions. *Modern Medicine* 99, 1975.